

## REMARKS/ARGUMENT

Claims 1-4, 7-8, 10-14, and 16-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Sikorski WO 00/38722 in view of Gurtler U.S. 5,773,021, Mulligan U.S. 5,128,142, Rowe US 2003/0099708, and Jin US 2004/0001888. This rejection is respectfully traversed for the following reasons.

The Examiner states at pages 5-6 of the Office Action that "Sikorski lacks the explicit teaching of amorphous drug, a composition in the form of an adsorbate, compositions comprising concentration-enhancing or dissolution-enhancing polymers, and the specific group of substrates recited in Applicants' claims." Since at least three of these four limitations are recited in all of the rejected claims, the Examiner concedes that Sikorski lacks at least three limitations of those claims.

In an effort to overcome these glaring deficiencies of the primary reference Sikorski, the Examiner cites the four secondary references of Gurtler, Mulligan, Rowe and Jin, essentially arguing that, since the missing elements are supposedly found in the secondary references, it would have been obvious to combine such elements with Sikorski to obtain the claimed invention. The Examiner's reliance on Rowe is unclear as to teaching any of the limitations missing from Sikorski, but if it is to support the proposition that increased bioavailability may require less drug, the point is conceded.

The Examiner broadly concludes that it would have been obvious to modify the composition of Sikorski to absorb drug "onto or into a cross-linked polymer (e.g. a cellulose derivative) to obtain the benefits of a controlled-release formulation taught by (Gurtler) or onto other conventional solid supports, such as silica or alumina (Jin)." Office Action, page 6. This reasoning is flawed for at least three reasons: (1) applicants do not claim substrates of a cross-linked polymer; (2) Gurtler does not disclose a substrate or matrix of a cross-linked polymer; and (3) there is nothing in either Gurtler or Jin to the effect that Gurtler's matrix polymers are equivalent to Jin's inorganic porous particle substrates. As to reason (3), Gurtler teaches a bioadhesive ophthalmic insert, or a drug-releasing device to be placed in and left in a human or animal eye. Column 1, lines 5-20. To achieve such a device, a "bioadhesive biocompatible polymer" is required. Column 2, lines 5-7. Such a polymer is "a natural or synthetic polymer capable of stable interaction with a biological substrate, such as the mucosa of the conjunctival sac." Column 2, lines 34-37. Following the Examiner's logic, one of ordinary skill would substitute Jin's metal oxide powders of alumina or silica for Gurtler's bioadhesive biocompatible polymers to be placed in a human eye. Surely the Examiner cannot be suggesting this as a plausible argument. But if the Examiner is suggesting such, it is respectfully submitted to be a

classic case of combining references such that the combination changes the principle of operation of the Gurtler device, which is impermissible in an obviousness analysis. See *In re Ratti*, 123 USPQ 349 (CCPA 1959).

Moreover, in his effort to show motivation to combine the teachings of the secondary references, Gurtler and Mulligan, the Examiner has relied upon applicants' own specification. In the case of Gurtler, the Examiner states "It is noted that the cross-linked polymer disclosed by Gurtler is identified by Applicants as being a concentration-enhancing polymer..." Office Action, page 6. In the case of Mulligan, which is relied upon as teaching PVP as a substrate, the Examiner states "Applicants have identified PVP as a dissolution-enhancing polymer." *Ibid.* Thus, the Examiner relies in part on his obviousness determination on knowledge gleaned only from applicants' disclosure, which is impermissible under the law pertaining to obviousness. *In re McLaughlin*, 170 USPQ 209, 212 (CCPA 1971).

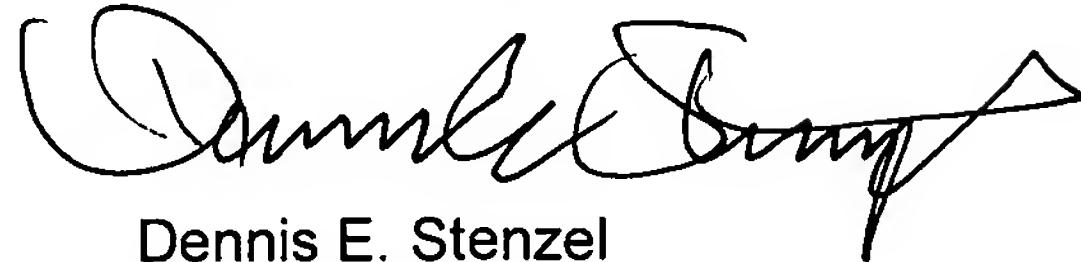
In contending that Jin teaches the claimed inorganic oxides, the Examiner has evidently deconstructed Jin's support, which is a lipid-loaded porous powder. See Jin at paragraphs [0056]-[0057] (Example 1), which describes the preparation of the support as impregnation of an alumina/Cab-O-Sil mixture with the melted lipid Gelucire. But stripping away the lipid from Jin's porous powder particles would render Jin's invention inoperable as there would be no carrier or matrix for the solid solution of drug and lipid to absorb into the channels of the porous particles. See Jin FIG. 1. It is well-settled law that if the proposed modification would render the prior art invention unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 221 USPQ 1125 (Fed Cir 1984).

The claims also stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting over copending Application No. 11/566,408 in view of Sikorski. Applicants file herewith a terminal disclaimer, thereby rendering this rejection moot.

Finally, the claims stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting over copending Application No. 11/795,743. Applicants note that Application No. 11/795,743 was filed as a 371 of a PCT application with an international filing date of January 30, 2006, claiming priority of February 8, 2005. Since the filing date of the instant application is October 6, 2003, Application No. 11/795,743 is not available as prior art relative to the instant application, and so withdrawal of this rejection is requested.

Early and favorable reconsideration is respectfully solicited.

Respectfully submitted,



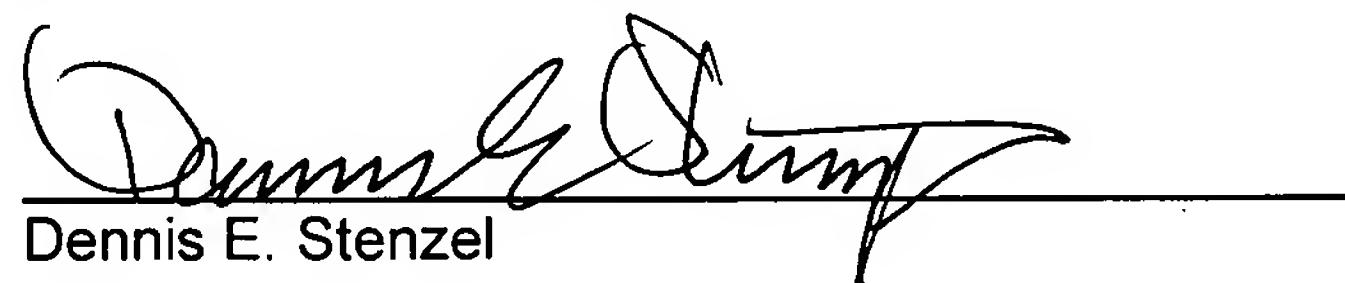
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